



UNITED STATES
NUCLEAR REGULATORY COMMISSION

WASHINGTON, D.C. 20555-0001

November 19, 1999

John I. H. Patterson, Ph.D.
President
Metorex, Inc.
Princeton Crossroads Corporate Center
250 Phillips Boulevard
Ewing, NJ 08618

Dear Dr. Patterson:

This letter is in response to your application dated July 14, 1999, requesting to amend Registration Certificate No. NR-0701-D-104-B for your x-ray fluorescence analyzer. We are in the process of evaluating your request. In order to continue our evaluation, we need additional information on the following issues:

1. In your letter dated July 14, 1999, you have indicated that the addendum "Modifications to SIPS Probe" described "the modifications planned." Please confirm that no other modifications have been made than those described in your application for amendment of Registration Certificate No. NR-0701-D-104-B.
2. Please specify the serial number for the first unit of the modified SIPS series. We need this information in order to distinguish the previous (unmodified) units from the units with the design changes described in your application.
3. Please replace Attachments 1A, 2A, and 3A in the application with drawings which show the major dimensions of the device and the end cap. In Attachment 3A, specify the thickness of the materials in the floating radiation shield.
4. Provide final drawings for those which you characterized in your application as "preliminary in nature."
5. Specify the physical/dimensional changes to the shutter because you have indicated that the "opening is slightly smaller." Provide a drawing if applicable.
6. Please delineate that the heat shield/end cap shown in Attachment 3A is the one which fits the modified SIPS device. Confirm that the end cap shown in Attachment 3 of the Certificate, dated November 12, 1998, fits only the devices prior to modification.
7. Specify the activity level of the Cd-109 source as well as the activity of the other source which were in the device at the time when the radiation profile measurements were taken. Indicate which source was open and which one was closed.
8. Provide information on the external radiation levels with a combination of sources similar to that in the Registration Certificate for the previous (unmodified) design.
9. Provide the dose rates when the end cap is mounted on the device.

- 10 15. In the drop tests, the shutter of the previous (unmodified) design did not open on impact, but after the functional test it remained open and did not close automatically. The shutter was manually closed to continue the drop tests. In the modified design the shutters are located closer to the probe end and, consequently, may be more susceptible to drop damage. Please provide information on drop test performance of the modified design; address drop tests from both 1 m and 2 m heights, similarly to the previous (unmodified) design.
- 11 16. Please describe or provide a drawing detail to illustrate how the shutter and the source holder are attached to each other in the drawing designated Attachment 2A (page 4)?
- 12 17. Specify whether the activity shown on the label is actual, nominal, or maximum?
- 13 18. Provide information, such as model number, manufacturer, calibration dates, window thickness or sensitivity, for the Geiger counter and for the scintillation counter which were used to make the measurements.
- 14 19. Provide current copies of the ISO approvals for your quality assurance program and for Metorex International Oy.

Please submit the requested information within thirty days of the date of this letter. If we have not received complete information within thirty days of the date of this letter, we will consider your application as having been abandoned by you. This is without prejudice to the resubmission of a complete application.

If you have any questions, please contact me at (301) 415-7904 or Dr. Seung Lee at (301) 415-5787.

Sincerely,

John P. Jankovich, Ph.D., Sr. Engineer
 Materials Safety and Inspection Branch
 Division of Industrial and
 Medical Nuclear Safety
 Office of Nuclear Material Safety
 and Safeguards

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